Version Number: 1 Effective Date: 05/13/2013	**Research & Development Policy** **151-30** **IRB REVIEW OF RESEARCH REPOSITORIES LOCATED AT THE SYRACUSE, CANANDAIGUA OR BATH VA MEDICAL CENTERS**	Supersedes Document Dated: NONE Expiration Date: 05/13/2017

I. PURPOSE

To set policies and procedures for appropriate review and approval of research bio- and/or data repositories (referred to here as "Research Repositories"), located at ("On-Site") within the VA Medical Centers overseen by the Syracuse VAMC R&D Program, including the **establishment** and **use** of research repositories and the use of human biological specimens obtained from either on- or off-site biorepositories.

II. SCOPE

This policy applies to data and/or human biological specimens collected during the course of a research protocol and maintained for use in future research. Such data/specimens must be kept in a research repository. This policy applies to research repositories established by local investigators. It also applies to local investigators who obtain data or specimens for research use from other research repositories (both internal within the facilities covered by the Syracuse R&D Service and all outside repositories).
This policy does not apply to research specimens and/or data collected for specific research protocols and **not** maintained for use in future research (i.e., for studies other than that under which they were collected).

III. POLICY

a. The Syracuse VAMC IRB must review and approve:

(1) The **establishment** of a research repository, including a review of the procedures for placing specimens/data into the research repository. All research repositories must have a principal investigator (PI), serving as the research repository director, who is responsible for submitting a research repository application to the IRB. The research repository director is responsible for the acquisition and maintenance of all specimens and/or data in the research repository.

(2) The research **use** of identifiable specimens/data obtained from research repositories. All requests to obtain specimens/data must be described in a research protocol and approved by the IRB. Such requests must have a PI (the recipient researcher) responsible for the use of the specimens/data. The research use of **de-identified** specimens/data may be considered exempt or may not meet the definition of human subjects research, and the Associate Chief of Staff/Research and Development (ACOS/R&D) or designee should be consulted, as other committee reviews may be required in place of IRB review and approval based on the requirements set forth in VHA handbook 1200.01 and/or the Research & Development Committee Standard Operating Procedures.

(3) The **contribution** of specimens/data from a new protocol to an established research repository. If the specimens/data being contributed are de-identified and/or do not meet the definition of human subjects, the ACOS/R&D or designee should be consulted to determine which committees must review and approve the contribution of the samples, based on the requirements set forth in VHA handbook 1200.01 and/or the Research & Development Committee Standard Operating Procedure.

b. If the research repository will be accessed and/or information from the repository disclosed for purposes preparatory to research, the research repository director must:

(1) Receive and maintain a copy of the request for information as preparatory to research approved by the IRB Chair, which documents that the access to the information in the research repository is only to prepare a protocol, that no PHI will be removed from the VA the repository is located, and that the PHI accessed is necessary for the preparation of the research proposed.

(2) Initiate a Data Use Agreement (DUA) for limited data sets or Data Transfer Agreement (DTA) for other data sets, when the data are transferred from the research repository to the recipient investigator. If the recipient investigator directly accesses the research repository, s/he must provide the research repository director with a copy of the approved request with an additional statement that only aggregate data will be recorded for the preparatory to research activity and no individually identifiable information will be recorded.

IV. DEFINITIONS: Please refer to SOP151-01, Appendix B for Definitions.

V. RESPONSIBILITIES AND PROCEDURES:

The **Research Repository Director** is responsible for submitting the IRB Application for Research Repository and a detailed research repository standard operating procedure (SOP) to the IRB for approval before establishing a research repository. Required components of the SOP are listed in section VI.b of this policy. Once a research repository is approved by the IRB, the research repository director is responsible for the acquisition and maintenance of all specimens and/or data, reviewing requests to access/release specimen(s)/data, keeping records, maintaining the privacy of subjects and the confidentiality of the data, ensuring specimens/data in the research repository are stored and secured according to VA requirements, and initiating data use agreements (DUAs) or data transfer agreements (DTAs) as needed with recipient investigators.

b. A **Recipient Investigator** is responsible for submitting a protocol and other appropriate paperwork to the IRB to obtain approval for each new proposed use of specimens/data stored in an approved local research repository. The recipient investigator assumes responsibility for assurances given to the IRB for the proposed study. Recipient investigators who are not researchers through the Syracuse, Canandaigua or Bath VAMCs must meet the requirements of their institution. The transfer of the specimens/data from a local research repository to a non-local recipient or non-local database must be in compliance with all VA privacy and information security requirements, including the establishment of a combined DUA-DTA. (Please consult with the ACOS/R&D for guidance on current requirements). Once such

transfer occurs, the local IRB is no longer responsible for reviewing and approving research protocols dealing with those specimens/data.

c. A **Contributing Investigator** is responsible for submitting the required IRB review items listed in the IRB Checklist for submission to the IRB for each new proposed submission of data/specimens to an approved local research repository.

d. The **Institutional Review Board** provides scientific and ethical oversight for research repositories. It is responsible for complying with all requirements of VHA Handbook 1200.05 in reviewing and approving:

(1) the standard operating procedures for the establishment and operation of research repositories;
(2) protocols submitted by recipient investigators for the research use of specimens/data held in established research repositories; and
(3) protocols submitted by contributing investigators for the addition of new research specimens/data to established research repositories.

The IRB is responsible for conducting a review of the research repository at least once each year.

e. The ACOS/R&D or designee is responsible for assisting the research repository director in developing standard operating procedures on the use of the data/specimens and for providing technical and scientific recommendations to the director and contributing and recipient investigators.

VI. ADMINSTRATIVE OVERSIGHT:

a. The IRB must approve any changes to a research repository, including the appointment of a new director, requests to combine research repositories, termination of a research repository, the appropriate destruction of specimens/data in line with an informed consent form, and location of research repositories.

b. **Standard Operating Procedures (SOP)** written by the research repository director as part of the application to establish a research repository must address the following (Also see Guidelines for creating SOP)

1) How records will be maintained.
2) Whether the specimens/data will be identifiable or de-identified. If the research repository includes de-identified specimens/data that may be re-identified, VHA Handbook 1200.12, section 6.c must be followed.
3) Policies and procedures for receiving specimens/data into, and releasing specimens/data from, the research repository.
4) Who may approve release of specimens/data to recipient investigators.
5) Mechanisms for verifying approval of the research by the IRB of record for the recipient investigator.
6) Administrative activities, such as hiring, training and supervising employees.
7) Conflict of interest.
8) Tracking of data.
9) Disclosure to subjects and conditions under which disclosure is or is not allowed.

10) Destruction of specimens/data due to the research repository's termination.\\

11) Access agreements (i.e., data use agreements).
12) Requiring and maintaining IRB and other committee approvals.
13) Security and oversight.

VII. REFERENCES:
VA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research,
VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research
VA Tissue Banking web site: http://www.research.va.gov/programs/tissue_banking/default.cfm

VIII. RESPONSIBILITY: Syracuse VAMC Research and Development Service will be responsible for the content, update, and recertification of this SOP.

IX. IMPLEMENTATION: May 2013

X. RESCISSION: NONE

XI. RECERTIFICATION: May 2017

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